

## **REMARKS**

Claims 64 and 66-89 are pending in the application.

Claims 64-73, 75-76 and 78 are cancelled from the application without prejudice.

Claims 74 is amended to include the features of cancelled claims 75-76 and 78 as well as additional pharmaceutical composition ingredient features.

The dependencies of claims 70, 79-80 and 83 are amended in view of the cancellation of certain application claims above.

The specification is amended above to correct the priority claim and to correct a typographical error.

No new matter is added to the application by way of these specification and claim amendments.

### **I. THE FORMAL DRAWING REQUIREMENT**

The examiner indicates that the application figures are informal and that formal drawings will be required when the application is allowed.

The applicant is prepared to submit formal drawings to the U.S. Patent Office upon receipt of a Notice of Allowance for this case.

### **II. THE SPECIFICATION OBJECTION**

The examiner objected to the specification for including a priority claim with application serial number errors and for including a typographical error.

The examiner's objections are overcome by amending the specification to correct the serial numbers of several applications listed in the priority claim and to correct the typographical error the examiner identified.

### **III. THE SECTION 112, 2<sup>nd</sup> PARAGRAPH REJECTIONS**

The examiner objected to claim 64 under the second paragraph of section 112 for being indefinite. The examiner's rejection is moot as claim 64 is now cancelled from the application.

#### **IV. THE DOUBLE PATENTING REJECTIONS**

The examiner rejected application claims for double patenting and for provisional double patenting over commonly owned U.S. patents and patent application.

The examiner's double patent rejections (both provisional and non-provisional) are moot in view of the applicant's amendment of claim 74 to include additional features of the claimed pharmaceutical composition. There are literally thousands of ingredients that may be used in pharmaceutical composition formulations. The preparation of a pharmaceutical formulation is often a trial and error process and the choice of excipients is not necessarily obvious or readily apparent based upon the pharmaceutical composition itself nor upon the desired administration method. Claim 74 is amended to recite a specific pharmaceutical composition. The composition is non-obvious over the claims of the applicants' earlier issued patents and filed patent applications. The withdrawal of the obviousness-type double patenting rejection in this case is therefore courteously solicited.

In addition, the examiner's provisional double patenting rejection is premature. Three of the four of the cited applications have filing dates after the filing date of the above-identified patent application. MPEP 804(I)(B)(1) indicates that when the provisional obviousness-type double patenting (PODP) rejection is the only rejection remaining in the earlier filed application, or if the PODP rejection is the only rejection remaining in the earlier and later filed applications, then the examiner should withdraw the PODP rejection in the earlier filed application and allow the earlier filed application to issue without a terminal disclaimer. Since that is the case here with respect to all provisional double patenting rejections except for the rejection over 10/629,368, the examiner should withdraw the PODP rejection and allow the current application to issue without a terminal disclaimer directed to the three later filed co-pending patent applications.

#### **V. THE ALLEGED CONFLICTING CLAIMS**

The examiner has taken the position that claims 64-89 of this application conflict under 37 CFR §1.78(b) with claims of co-pending patent application nos. 10/629,368; 11/070,768; 11/253,322; and 11/588,834 and that the elimination of such claims from all but one application may be required in the absence of good and sufficient reasons for their retention during pendency

in more than one application. The examiner goes on to require the Applicant to cancel the conflicting claims or to maintain a clear line of demarcation between the applications.

As an initial matter, the Applicant disagrees with the examiner's position that the applications include "conflicting claims." None of the claims are identical, and all of the claims of the different applications are patentably distinct from one another. In addition, the Applicant intends to maintain a clear line of demarcation between the applications and their claims. For at least these reasons, the examiner's position that the applications include "conflicting claims" is traversed.

## **VI. RELATED APPLICATIONS AND PATENTS**

The applicant of this application has several issued patents and a variety of currently pending patent applications that are related to the compositions and administration methods discussed in the pending application by priority and by subject matter. A listing of the related patent applications is found at Appendix A. The applicant has cited all of the patents and patent applications in Information Disclosure Statements filed in this case. The applicant has not, however, cited all prosecution documents from the applications and patents, - Office Actions and applicants' Office Action Replies - in an IDS primarily because the same examiner is responsible for examining all of the related pending applications and has examined most of the related applications that have issued as patents. The applicant is more than willingly to bring all prosecution documents in related applications and patents to the attention of the examiner by way of an IDS should the examiner so request.

### CONCLUSION

The examiner's specification and claims objections are overcome by the specification and claim amendments made above. Favorable reconsideration and allowance of all pending application claims is courteously solicited.

Should the Examiner have any questions, he is invited to contact the undersigned attorney at (312) 913-2123.

Respectfully submitted,

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